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GLADYS H MONROY  
MORRISON AND FOERSTER LLP  
755 PAGE MILL ROAD  
PALO ALTO CA 94304-1018

EXAMINER

VANDER VEGT, F

ART UNIT

PAPER NUMBER

1644

DATE MAILED:

08/16/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/309,199

Applicant(s)

Assemacher et al

Examiner  
F. Pierre VanderVegt

Group Art Unit  
1644



- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), ~~or thirty days, whichever is longer~~, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1-73 is/are pending in the application.
- Of the above, claim(s) 51-73 is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-50 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

- ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4 & 5
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

### DETAILED ACTION

This application claims priority to provisional application 60/085,136.

Claims 1-73 are currently pending in this application.

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#### *Election/Restriction*

1. Applicant's election without traverse of Group I, claims 1-50, drawn to a method for preparing and/or detecting surface-modified antigen-specific T cells, in Paper No. 8 is acknowledged.

10 Claims 51-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions. Election was made **without** traverse in Paper No. 8.

#### *Claim Rejections - 35 USC § 112*

15 2. Claims 1-50 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method when using a high viscosity or gel forming medium such as gelatin or agarose or alginate, does not reasonably provide enablement for the claimed method absent the use of said ingredients. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. .

20 Briefly, the claims are drawn to obtaining an enriched population of antigen-specific T cells based upon the production of response indicators and capture on the cell surface. The claims are not enabled for the identification for identifying such a population of T cells. The Manz et al reference, which includes the instant inventors among it's authors, (3 on form PTO-1449 filed 12/21/1999) discloses, "In normal medium the secreted product will readily diffuse away and, in the approach described here, will label all cells covered with the affinity matrix, whether they are  
25 secreting or not" (page 1923, first column in particular). Manz et al further discloses that a solution to this problem is to perform the assay in a high viscosity media (page 1923, first column in particular). Manz et al broadly characterizes the disclosed method in stating: "Crossfeeding of the secreted products to other cells is prevented by decreasing the permeability of the incubation

media" (see Abstract in particular). Manz et al thus discloses that there is a need for high viscosity media to practice the instant invention. The instant specification does not disclose conditions under which the high viscosity medium requirement can be overcome. Therefore, the enablement provided by the instant specification is not commensurate with the scope of claims that do not recite the aforementioned ingredients as a component of the claimed method.

In view of the quantity of experimentation necessary, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue trials and errors to practice the claimed invention and this is not sanctioned by the statute.

3. Claims 5-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 5-7 are drawn to the separation of cells secreting product from other cells in the population by fluorescent sorting [claim 5] or magnetic sorting [claims 6-7]. The claims are not enabled. Base claim 1 requires the attachment of the label moiety to the surface of all cells in the population prior to secretion of the product by the activated T cells with the intent of capturing the product on the surface of the cell secreting it. The secretion of product does not have any bearing as to whether the label is present on a cell or not. Since all cells are already labeled, it would not be possible to separate only those cells which secrete and capture product.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-4, 8, 12, 14-17, and 22-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Manz et al (3).

The Manz et al reference teaches a method for attaching an antibody label moiety to the surface of T cells via biotin-avidin interaction and capturing product secreted by the T cell (see entire document). The prior art teaching anticipates the claimed invention. Claim 12 is included because the biotin moiety attaches to proteinaceous components of the cell surface.

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5. Claims 1-4 and 8-50 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 94/09117 by Miltenyi et al (12).

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The '117 document teaches a method for attaching a label moiety onto the surface of a cell for capturing product secreted by the cell (see entire document). The '117 document teaches bispecific antibodies as the capture moiety (page 11, line 29 to page 12, line 9 in particular), lipid anchors (page 10, 20-23 in particular), antibody coupling to components on the cell surface (page 10, line 23 to page 11, line 2 in particular) and use of linking moieties (page 10, lines 12-19 in particular). The prior art teaching clearly anticipates the claimed invention.

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### ***Conclusion***

6. Only the English abstract of reference 44 on Applicant's form PTO-1449 filed September 10, 1999 has been considered because the remainder of the reference is in French. The PTO-1449 has been marked accordingly.

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7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

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8. Papers related to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. Papers should be faxed to Group 1640 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax phone number for official documents to be entered into the record for Art Unit 1644 is (703)305-3014.

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Any inquiry concerning this communication or earlier communications from the Examiner should be directed to F. Pierre VanderVegt, whose telephone number is (703)305-6997. The

Examiner can normally be reached Tuesday through Friday and odd-numbered Mondays (on year 2000 366-day calender) from 6:30 am to 4:00 pm ET. A message may be left on the Examiner's voice mail service. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ms. Christina Chan can be reached at (703)308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist, whose telephone number is (703)308-0196.

F. Pierre VanderVegt, Ph.D.  
Patent Examiner  
Technology Center 1600  
August 14, 2000



F. PIERRE VANDERVEGT  
PATENT EXAMINER